UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA INDIRECT PURCHASER ANTITRUST LITIGATION **[SBF Action]**	**No.: 1:15-cv-6549** **[PROPOSED] JOINT PRETRIAL ORDER**

Plaintiff Sergeant Benevolent Association Health & Welfare Fund ("Plaintiff" or "SBA") and defendants Forest Laboratories ("Forest") and Merz Pharmaceuticals ("Merz," and together with Forest, "Defendants"), having conferred among themselves and with the Court pursuant to Federal Rule of Civil Procedure 16, hereby submit the proposed Joint Pretrial Order. The parties agree that any Court decision on forthcoming Motions *in Limine* and other motions may warrant revising portions of this Pretrial Order, including the issues to be tried, the parties' exhibits, the parties' witness lists, the parties' deposition designations, including counter-designations, and the parties' contentions.

I. NATURE OF THE CASE

This is an antitrust action arising under certain state antitrust[1] and consumer protection laws,[2] and also seeking equitable relief,[3] which challenges alleged anticompetitive conduct relating to the market for brand and generic memantine hydrochloride sold in the United States under the

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[1] Antitrust laws in the following states are at issue: Arizona, California, District of Columbia, Hawaii, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, West Virginia, and Wisconsin.

[2] Consumer protection laws in the following states are at issue: California, Florida, Idaho, Illinois, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, and Utah.

[3] Unjust enrichment (equitable relief) in the following jurisdictions: Alabama, Arizona, California, District of Columbia, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, and West Virginia.

brand name Namenda (the "Relevant Market"). Namenda is indicated for the treatment of patients diagnosed with moderate-to-severe Alzheimer's disease. The parties could not reach agreement on the Nature of the Case therefore each position is set forth below.

A. Plaintiff's Position

SBA, on behalf of itself and the Class (as defined by Order of the Court), alleges that the effect of the various payments and entry-date terms of Defendants' Namenda IR patent settlement with Mylan was an unlawful "reverse payment" that thwarted generic competition in the "Relevant Market." Defendant Forest possessed monopoly power in the Relevant Market at all times during the Class Period. Both Forest and Merz were parties to the settlement agreement with Mylan. SBA claims that Defendant Forest acted unlawfully to maintain its monopoly power, and that Defendant Merz acted with specific intent to exclude generic competition and thereby unlawfully conspired with Forest to maintain Forest's monopoly.

More specifically, SBA contends that in 2010, Forest and Merz, on the one hand, and Mylan, on the other, entered into an agreement to settle a lawsuit regarding the validity and effect of Merz's patent which allegedly protected Forest's Namenda products from competition. At the same time, Forest and Mylan agreed to amend a contract to market an authorized generic version of Forest's Lexapro drug ("Lexapro Amendment"), and Forest agreed to pay Mylan additional compensation under that agreement. The Plaintiff Class contends that payments and terms of the Mylan patent settlement and the Lexapro Amendment combined constituted a "large and unjustified" payment under *FTC v. Actavis*, 570 U.S. 136 (2013), and thus an illegal pay-for-delay agreement to keep the generic version of Namenda off the market. The Plaintiff Class seeks damages for their claims under state antitrust and consumer protection statutes, including multiple (e.g., double, treble, or punitive) damages where appropriate, as well as equitable relief consisting of the disgorgement of the profits by which Defendants were wrongfully enriched.

B. Defendants' Position

Forest and Merz deny that their conduct violated any applicable law or otherwise injured Plaintiff or the Class. Specifically, Forest and Merz contend that the Mylan patent Settlement Agreement provided for earlier generic entry than otherwise would have occurred, and that neither the Mylan Settlement Agreement nor the Lexapro Amendment contained a large and unexplained reverse payment to delay generic Namenda. Forest contends the Lexapro Amendment was a fair value arm's-length business deal through which Forest expected to receive more value than it provided to Mylan. Merz further contends that it had no involvement with the Lexapro Amendment—Merz did not negotiate it, did not sign it, and made no direct or indirect payments under it. Merz also contends that it had no knowledge of the Lexapro Amendment's terms prior to its execution. Because it had no involvement with the Lexapro Amendment, Merz contends that it could not have conspired with Forest with specific intent to maintain Forest's monopoly through a large and unexplained payment to delay generic entry. Forest and Merz also deny that the conduct challenged by SBA and the Class had any impact on the marketplace, the timing of generic entry by Mylan or any other generic manufacturer, or the prices Class members paid for branded or generic Namenda products. And Forest and Merz maintain that SBA and the Class have failed to meet their burden of presenting non-speculative proof of injury and damages.

II. JURY/NON-JURY

The parties agree that the case shall be tried by a jury, and the parties request that the trial be timed using a chess clock. In addition, the parties have the following statements.

A. Plaintiff's Position

Plaintiff estimates that the trial will take approximately two (2) weeks. Plaintiff requests that each side be allocated 20 hours each, not including opening and closing arguments. Plaintiff proposes that each side take 45 minutes for opening argument and 45 minutes for closing argument.

In addition, Plaintiff proposes 20 minutes for rebuttal after Defendants' closing. The proposed time for openings and the inclusion of Plaintiff's rebuttal is consistent with the Court's instruction in the Direct Purchaser matter. *In re Namenda Direct Purchaser Antitrust Litigation*, October 10, 2019, Hearing Tr. at pp. 142:2-4; 143:23-144:15.

B. Defendants' Position

Defendants request that each side be allocated thirty-five (35) hours. Defendants request that each side must complete their case, including opening statements, examination of witnesses, and closing arguments, in the allotted time. Of the 35 hours allocated per side, Defendants propose that Plaintiff is allocated 60 minutes for opening argument and Defendants, combined, are allocated 70 minutes. Defendants further propose that of the 35 hours allocated per side, Defendants, combined, are allocated 105 minutes for closing argument and Plaintiff is allocated 90 minutes for closing argument, with Defendants presenting their closing arguments first, followed by Plaintiff's closing argument. *In re Namenda Direct Purchaser Antitrust Litigation,* October 10, 2019 Hearing Tr. at pp. 145:5-12. Defendants further request that if evidentiary disputes must be resolved by the Court, the time each party takes to argue the dispute will be charged against it. If the Court determines that the dispute was frivolous or brought in bad faith, the Court may charge the losing party in the Court's discretion with all the time dedicated to resolving the issue.

III. STIPULATED FACTS

The parties stipulate as follows:

A. Venue

1. For the purposes of this action, the parties agree venue is proper in the United States District Court for the Southern District of New York.

B. Forest's New Drug Application for Namenda

2. Memantine hydrochloride is prescribed to treat patients with moderate-to-severe Alzheimer's disease.

3. In December 2002, Forest submitted New Drug Application (''NDA") No. 21-487 to the United States Food and Drug Administration ("FDA"), seeking approval to market memantine hydrochloride tablets (5mg and 10mg)—branded as Namenda—for the treatment of moderate-to-severe Alzheimer's Disease.

4. On October 16, 2003, the FDA approved Forest's NDA for twice-daily immediate release ("IR") tablets memantine hydrochloride as an NMDA-receptor blocker for use in patients with moderate-to-severe dementia of the Alzheimer's type, which Forest markets under the brand name Namenda.

5. In January 2004, Forest commercially launched Namenda IR tablets in the United States.

C. The '703 Patent

6. The Merz Defendants own Patent No. 5,061,703 ("the '703 patent") which claims methods of using memantine hydrochloride to treat moderate-to-severe Alzheimer's disease.

7. The '703 patent, issued on October 29, 1991, is entitled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia."

8. In June 2000, Forest obtained an exclusive license to market a memantine hydrochloride product in the United States under Merz's '703 patent.

9. The '703 patent was originally set to expire on April 11, 2010.

10. On March 3, 2009, the United States Patent and Trademark Office extended the expiration date of the '703 patent to April 11, 2015.

D. The Memantine License Agreement

11. On June 28, 2000, Merz and Forest entered into the License and Cooperation Agreement (the "Memantine License Agreement").

12. Pursuant to the Memantine License Agreement, Merz granted Forest an exclusive license to use the '703 Patent and certain Merz know-how to manufacture, produce, market, distribute, sell, and use memantine in the United States.

13. In furtherance of the exclusive rights and license that Merz granted to Forest under the Memantine License Agreement, Merz agreed that it would not "during the continuance of [the Memantine License Agreement], market, distribute, or sell any pharmaceutical formulations of Memantine" in the United States.

E. Patent Reexamination and the Patent Term Extension

14. On August 18, 2004, Merz filed a request with the PTO for reexamination of the '703 patent.

15. The PTO instituted reexamination of the '703 patent on October 18, 2004.

16. On November 7, 2006, the PTO issued an Ex Parte Reexamination Certificate for the '703 patent.

17. On March 3, 2009, the PTO issued a Notice of Final Determination that the '703 patent was eligible for a patent term extension of five years. In connection with the PTO's March 3, 2009, Notice of Final Determination, "[a] determination ha[d] been made that U.S. Patent No. 5,061,703, which claims a method of using the human drug product NAMENDA® (memantine hydroch[]loride), is eligible for patent term extension under 35 U.S.C. §156." On March 18, 2009, the PTO issued a Certificate Extending Patent Term under 35 U.S.C. § 156 for the '703 patent.

18. The PTO's Patent Term Extension ("PTE") extended the expiration date of the '703 patent from April 11, 2010 to April 11, 2015.

19. On July 7, 2011, Forest submitted an application to the FDA seeking to conduct studies to support the safety and efficacy of memantine as a treatment for pediatric patients with autism.

20. On June 16, 2014, the FDA granted pediatric exclusivity for memantine hydrochloride to Forest. An additional six months of U.S. market exclusivity attached to the '703 patent.

21. The final expiration date of the '703 patent, accounting for the extensions the PTO and FDA granted it, was October 11, 2015.

F. '703 Patent Litigation

22. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the "Hatch-Waxman Act"), an applicant seeking approval to market a generic drug before the expiration of patents related to the brand-name drug that the applicant seeks to copy must provide in its application a "certification" that a patent submitted to the FDA by the brand-name drug's sponsor and listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) is, in the applicant's opinion, invalid, unenforceable, or will not be infringed by the generic product. This certification is called a "paragraph IV certification."

23. Under the Hatch-Waxman Act, the first company or companies to submit an Abbreviated New Drug Application ("ANDA") that (1) is determined by the agency to be "substantially complete" upon submission and (2) contains a paragraph IV certification to at least one of the patents listed in the Orange Book, may be eligible for the exclusive right to market the generic drug for 180 days. Where multiple companies fulfill these requirements on the same date, each of the companies is considered a first filer and their 180-day "exclusivities" run concurrently,

meaning they share the right to market a generic version of the brand for that period of time. Once the 180-day period runs out, other companies are permitted to enter the market.

24. Under the Hatch-Waxman Act, in order to challenge a patent in court, the applicant that submitted a paragraph IV certification must notify the brand product sponsor and any patent holder of the submission of the ANDA and the patent challenge. If the brand product sponsor or patent holder files an infringement suit against the applicant within 45 days of the ANDA notification, the FDA generally postpones final approval of the ANDA for 30 months unless the patent expires or is judged invalid or not infringed before that time. This 30-month postponement, commonly referred to as the "30-month stay," gives the brand product sponsor and patent holder a prescribed amount of time to litigate patent rights in court.

25. Fourteen of the generic applicants shared first-filer status. Those generic applicants may be referred to in this case as Amneal, Barr, Cobalt, DRL, Genpharm, Lupin, Mylan, Orchid, Ranbaxy, Sun, Synthon, Teva, Upsher-Smith, and Wockhardt (the "First-Filer Generic Manufacturers").

26. Because of the first-mover advantage, the first generic manufacturer (or group of generic manufacturers) to launch a generic product is usually able to capture and maintain a larger share of the market than later-entering generic manufacturers.

27. Forest and Merz commenced litigation against each of the First-Filer Generic Manufacturers, as well as later-filing generic manufacturers like Apotex, alleging that the Generic Challengers' proposed generic memantine hydrochloride products and their methods of use would infringe the '703 patent if marketed before the '703 patent expired.

28. These patent infringement lawsuits triggered an automatic 30-month stay of the FDA regulatory review of the generic manufacturers' ANDA applications.

29. The court eventually consolidated the patent infringement lawsuits against the Generic Challengers into a single action (the "'703 Patent Litigation").

30. The judges overseeing the '703 Patent Litigation were Chief Judge Gregory M. Sleet and Magistrate Judge Leonard P. Stark.

G. Terms of the '703 Patent Litigation Settlement Agreements with the Settling Generic Challengers

31. Merz and Forest settled the '703 Patent Litigation with Amneal, Cobalt, Sun, Teva, Upsher-Smith, Wockhardt, Dr. Reddys, Lupin, Orchid, and Mylan (the "Settling Generic Challengers").

32. On September 1, 2009, Forest and Merz settled their patent-infringement lawsuit against Amneal ("Amneal Settlement"). The Amneal Settlement stated that "[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Amneal $150,000 to defray a portion of the paid attorney fees and costs that Amneal has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[]."

33. On September 8, 2009, Forest and Merz settled their patent-infringement lawsuit against Upsher-Smith ("Upsher-Smith Settlement"). The Upsher-Smith Settlement stated that "[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Upsher-Smith $600,000 to defray a portion of the paid attorney fees and costs that Upsher-Smith has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[]."

34. On September 10, 2009, Forest and Merz settled their patent-infringement lawsuit against Wockhardt ("Wockhardt Settlement"). The Wockhardt Settlement stated that "[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall

pay Wockhardt $1,000,000 to defray a portion of the paid attorney fees and costs that Wockhardt has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[].”

35. On October 15, 2009, Forest and Merz settled their patent-infringement lawsuit against Cobalt (“Cobalt Settlement”). The Cobalt Settlement stated that “[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Cobalt $1,500,000 to defray a portion of the paid attorney fees and costs that Cobalt has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[].”

36. On November 3, 2009, Forest and Merz settled their patent-infringement lawsuit against Teva (“Teva Settlement”). The Teva Settlement stated that “[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Teva $1,000,000 to defray a portion of the paid attorney fees and costs that Teva has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[].”

37. On November 13, 2009, Forest and Merz settled their patent-infringement lawsuit against DRL (“DRL Settlement”). The DRL Settlement stated that “[i]n partial consideration of Plaintiffs’ saved legal fees associated with the Action and DRL’s expended legal fees associated with the Action, Plaintiffs shall reimburse DRL’s attorney fees and costs up to a maximum total reimbursement of up to $1 million[].” Forest and Merz ultimately paid $849,732.34.

38. On December 11, 2009, Forest and Merz settled their patent-infringement lawsuit against Lupin (“Lupin Settlement”). The Lupin Settlement stated that “[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Lupin

$1,000,000 to defray a portion of the paid attorney fees and costs that Lupin has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[].”

39. On March 23, 2010, Forest and Merz settled their patent-infringement lawsuit against Orchid (“Orchid Settlement”). The Orchid Settlement stated that “[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Orchid $2,000,000 to defray a portion of the paid attorney fees and costs that Orchid has already expended in the Action and the Consolidated Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[].”

40. On July 21, 2010, Forest and Merz settled their patent-infringement lawsuit against Mylan (“Mylan Settlement”). The Mylan Settlement stated that “[g]iven that the Settlement Agreement and this License Agreement will fully resolve the Action, Plaintiffs shall pay Mylan $2,000,000 to defray a portion of the paid attorney fees and costs that Mylan has already expended in the Action and to reflect a portion of the saved attorney fees and costs that Plaintiffs will not have to expend in the Action[].”

41. The Settlement Agreements contained licenses (“License Agreements”) permitting each Settling Generic Challenger to launch a generic memantine hydrochloride product 3 calendar months prior to the expiration of the ‘703 Patent, including any extensions and/or pediatric exclusivity (the “Launch Date”), provided that the Settling Generic Challenger obtained final approval to launch from the FDA.

42. Pursuant to the License Agreements, each Settling Generic Challenger could launch their generic memantine hydrochloride products prior to the Launch Date if: (i) Merz and Forest entered into an agreement with another generic company permitting them to launch sooner than 3

calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity; (ii) another generic company obtained a final court decision of non-infringement and/or invalidity of the '703 patent; or (iii) another generic company launched "at risk."

43. These clauses made it such that once one Settling Generic Challenger entered the market, any other Settling Generic Challenger could enter the market for Namenda IR to the extent it also obtained final FDA approval.

44. Pursuant to an August 3, 2007, Memorandum of Understanding between Merz and Forest (the "MOU"), Forest and Merz evenly split the legal fees and the payments made to each Settling Generic Challenger to settle the '703 patent litigation.

H. Terms of the '703 Patent Litigation Settlement Agreements with Apotex and Torrent

45. On September 8, 2009, Forest and Merz settled their patent-infringement lawsuit against Apotex ("Apotex Settlement").

46. The Apotex Settlement provided that each party remained responsible to pay its own costs and expenses in connection with the '703 Patent Litigation.

47. The Apotex Settlement permitted Apotex to launch its generic memantine hydrochloride product on the date the '703 Patent, including any extensions and/or pediatric exclusivity, expired, provided it had FDA approval to do so.

48. On December 7, 2009, Forest and Merz entered into a settlement with Torrent, which included Torrent Pharma Inc. ("Torrent Settlement"). The Torrent Settlement stated that "the Parties desire to enter into this Agreement to avoid potential litigation regarding claims of patent infringement."

49. The Torrent Settlement provided that each party remained responsible to pay its own costs and expenses in connection with the execution of the agreement.

50. The Torrent Settlement permitted Torrent to launch its generic memantine hydrochloride product on the date the '703 Patent, including any extensions and/or pediatric exclusivity, expired, provided it had FDA approval to do so.

I. Forest/Alphapharm Lexapro Agreement

51. Escitalopram oxalate ("escitalopram") is the active pharmaceutical ingredient in the branded drug Lexapro, which is indicated for the treatment of major depressive disorder.

52. Lexapro was developed by Forest and H. Lundbeck A/S ("Lundbeck"), a Danish pharmaceutical firm.

53. On May 24, 2002, Lundbeck and Forest entered the "S-enantiomer License Agreement," whereby Lundbeck granted Forest a license to market Lexapro in the United States.

54. Forest submitted an application to the FDA to market Lexapro called "NDA 02-1323", and the FDA approved Forest's application on August 14, 2002.

55. In September of 2002, Forest launched Lexapro in the United States.

56. On October 3, 2005, Forest and Alphapharm Pty, Ltd. ("Alphapharm") entered into a Distribution and Supply Agreement (the "Original Lexapro Agreement") which would allow Alphapharm to market an authorized generic version of Lexapro ("Generic Lexapro").

57. An authorized generic drug is a drug manufactured and marketed as a generic under the same regulatory approval application number as a brand drug.

58. Under the Original Lexapro Agreement, Alphapharm was permitted to enter the market on February 27, 2012.

59. Under the Original Lexapro Agreement, Forest reserved all rights with respect to the manufacture of Generic Lexapro.

60. Teva, the sole first-filing ANDA applicant for escitalopram, was permitted to launch a generic escitalopram product on March 12, 2012, two weeks after Alphapharm was permitted to launch authorized generic escitalopram, and 180 days before later-filing ANDA applicants could launch competing products.

61. Alphapharm had the right to terminate the Original Lexapro Agreement one year following the launch of the Lexapro authorized generic as long as it gave 120 days prior written notice to Forest.

62. The Original Lexapro Agreement contained an automatic renewal provision.

J. Forest/Mylan Lexapro Agreements

63. Mylan acquired Alphapharm in 2007.

64. Mylan received tentative approval from the FDA to market generic escitalopram oxalate tablets on May 31, 2006.

65. On July 21, 2010, Forest, Alphapharm, and Mylan (Mylan as an assignee of Alphapharm) executed the Amendment to Distribution and Supply Agreement (Generic Lexapro) (the "Lexapro Amendment").

IV. PARTIES' CONTENTIONS

Plaintiff's contentions are appended hereto as Exhibit IV.A.

Defendants' contentions are appended hereto as Exhibit IV.B.

V. ISSUES TO BE TRIED

A. Plaintiff's Position

1. Did Defendants enter into a reverse payment agreement with Mylan that unreasonably restrained trade?

2. Was the 2010 Lexapro Amendment a "side deal" to settling the Namenda IR patent litigation?

3. Did the 2010 Lexapro Amendment "demonstrate 'that [Forest] [sought] to induce [Mylan] to abandon its claim with a share of [Forest's] monopoly profits that would otherwise be lost in the competitive market[?]'" *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 197 (S.D.N.Y. 2018) (quoting *FTC v. Actavis*, 570 U.S. 136, 154, 158 (2013)).

4. Do the anticompetitive effects of the 2010 Lexapro Amendment outweigh Forest's proffered procompetitive justifications?

5. Did the Lexapro Amendment's financial terms extend Defendants' Namenda patent exclusivity longer than if the Namenda patent case had been settled without those payments, or had gone to trial?

6. When could generic versions of Namenda IR have entered the market in the absence of the alleged large and unjustified payments made to delay generic competition?

7. What are the total overcharge damages of the Plaintiff Class before allowing for multiple (double or treble) damages?

8. By how much were Defendants unjustly enriched as a result of their actions toward the Plaintiff Class?

B. Defendants' Position

1. Were the Lexapro Amendment and the Mylan Settlement Agreement two separate agreements or one agreement?

2. Were the payments made by Forest to Mylan under the Lexapro Amendment explained by the benefits Forest and/or Mylan expected to receive?

3. Did the Lexapro Amendment, viewed together with the Mylan Settlement Agreement, involve a reverse payment from Forest to Mylan that was "large" as defined by *Actavis*?

4. Absent any "large" and "unexplained" reverse payment, would Mylan have either (1) entered into a no-payment patent settlement with Defendants with a November 2012 entry date, or (2) litigated and prevailed in the Namenda IR patent litigation, through appeal, by June 2012?

5. If, absent any large and unexplained payment, Mylan or other generics would have entered the market earlier than they in fact did, which generics would have entered earlier, when would they have entered, and would they, from a regulatory and manufacturing perspective, have had the ability to successfully enter at that time?

6. To the extent any large and unexplained reverse payment from Forest to Mylan led to delays in generic entry, were such delays explained by procompetitive benefits or business justifications?

7. If the jury finds that Forest made a large and unexplained reverse payment to Mylan that had an anticompetitive effect on the relevant market, did Merz conspire with Forest to make the large and unexplained payment with the specific intent to maintain Forest's monopoly?

8. If entry by manufacturers of generic Namenda IR would have occurred sooner absent the large and unexplained payment, what effects would this have had on purchasing behavior and prices paid by Plaintiff or Class members?

9. Has Plaintiff proven that its damages calculations, including the key assumptions underlying such calculations, are reliable, and if so what amount, if any, should be awarded to compensate for alleged overcharges to Plaintiff and the Class?

VI. PLAINTIFF'S EXHIBITS

1. Plaintiff's list of exhibits that it may offer at the jury trial is attached as Exhibit VI.A. Plaintiff's trial exhibits are identified with PX numbers, starting at PX-0001. Because

Defendants twice refused[4] to agree to a stipulation that excluded "expert materials relied on" from the exhibit list—a substantially identical stipulation endorsed by the Court in the DPP case (ECF No. 672)[5]. Plaintiff's exhibit list contains over 1000 exhibits that are "expert materials relied on" and the parties' exhibit lists could be streamlined with such a stipulation. Plaintiff's exhibit list should not be construed as a waiver of any objection to any exhibit on Defendants' exhibit list or to Defendants' use of any exhibits on their exhibit list or on Plaintiff's exhibit list for any purpose at trial or otherwise. Plaintiff states that certain documents identified in its exhibit list, while admissible if proffered by Plaintiff, would not be admissible if offered by Defendants. By listing a particular version of a document, Plaintiff in no way waive its right to refer to other versions of that document at trial. Plaintiff also reserves the right to amend and supplement Plaintiff's list as circumstances may warrant.

2. In addition to the exhibits listed in Plaintiff's exhibit list, Plaintiff reserves the right to submit charts, graphs, summaries, blowups, and other demonstrative exhibits. Plaintiff also reserves the right to submit exhibits in addition to those listed in their exhibit list in rebuttal, impeachment, or in light of any subsequent ruling by the Court or in response to any supplemental exhibits offered by Defendants.

3. Plaintiff further reserves the right to offer any exhibits set forth in the parties' joint exhibit list, even if not explicitly identified in this list.

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[4] *See* August 10, 2021 email from L. Fanning to counsel for the Defendants and August 11, 2021 email from O. Adendorff rejecting the stipulation. *See also*, September 29, 2021 email from L. Fanning to T. Gerasimow and O. Adendorff renewing the request to stipulate, which was rejected again on September 30, 2021. Attached as Exhibit VI.B.

[5] *See In re Namenda Direct Purchaser Antitrust Litig.*, ECF No. 672.

VII. DEFENDANTS' EXHIBITS

Defendants' list of exhibits that it may offer at the jury trial is attached as Exhibit VII.B. Defendants' trial exhibits will be identified with DX numbers, starting at DX-0001. Defendants' exhibit list should not be construed as a waiver of any objection to any exhibit on Plaintiff's exhibit list or to Plaintiff's use of any exhibits on their exhibit list or on Defendants' exhibit list for any purpose at trial or otherwise. Defendants state that certain documents identified in their exhibit list, while admissible if proffered by Defendants, would not be admissible if offered by Plaintiff. By listing a particular version of a document, Defendants in no way waive their right to refer to other versions of that document at trial. Defendants also reserve the right to amend and supplement this list as circumstances may warrant.

In addition to the exhibits listed in Exhibit VII.B, Defendants reserve the right to submit charts, graphs, summaries, blowups, and other demonstrative exhibits. Defendants also reserve the right to submit exhibits in addition to those listed in Exhibit VII.B in rebuttal, impeachment, or in light of any subsequent ruling by the Court or in response to any supplemental exhibits offered by Plaintiff.

Defendants further reserve the right to offer any exhibits set forth in the parties' joint exhibit list, even if not explicitly identified in this list.

VIII. STIPULATIONS AND OBJECTIONS WITH RESPECT TO EXHIBITS

The parties have not yet reached agreement on the Joint Exhibit List or on additional stipulations and objections on the exhibits. The parties propose to supplement the PTO in that regard. The parties' objections to exhibits are detailed in the exhibit lists.

IX. PLAINTIFF'S WITNESS LIST

Listed below are all of the witnesses Plaintiff intends to call at trial, whether live or by video. Plaintiff's deposition designations with objections are included as Exhibit IXA. In addition

to the witnesses listed below, Plaintiff reserves the right to call in their case-in-chief witnesses listed on Defendants' witness list. Plaintiff further reserves the right to revise this list in accordance with any subsequent Court rulings or for good cause shown.

Plaintiff further reserves the right to call: (1) additional witnesses to provide foundational testimony should any party contest the authenticity or admissibility of any material proffered at trial; (2) additional witnesses necessitated by any of the Court's pretrial or trial rulings, or to respond to issues raised after the submission of witness lists. Plaintiff objects to Defendants' reservation of rights on substituting witnesses, see (3) below in Section X, Defendants' Witness List and the remainder of the paragraph.

Live[6]

1. A corporate representative of the Forest and Merz Defendants
2. Any live witness identified on Defendants' live witness list.
3. Custodian of Records for Defendants
4. Errol Ogman
5. Dr. Russell Lamb
6. Dr. William Vogt
7. Laura Craft
8. Susan Marchetti
9. Dr. Thomas McGuire
10. Dr. Jacob Holzer
11. Dr. Michael Davitz

By Video

[6] The identification of a witness on this list is not an indication or representation that Plaintiff controls a witness or can compel his or her attendance at trial, and thus, Plaintiff reserves all rights to play or read the deposition testimony of any witness on this list who does not appear live at trial.

1. Alexandra Bonnelli
2. Bob Lahman
3. Bharati Nadkarni
4. Jinping McCormick
5. Eric Agovino
6. June Bray
7. Philip Burchard
8. Robert Carnevale
9. Maureen Cavanaugh
10. Katrina Curia
11. Mark Devlin
12. Kapil Gupta
13. Sanjay Gupta
14. Patrick Jochum
15. Staci Julie
16. Peter Ludwig
17. Rachel Mears
18. Lauren Rabinovic
19. Charles Ryan
20. Seth Silber
21. Ajay Singh
22. Julie Snyder
23. David Solomon
24. Diana Wilk

X. DEFENDANTS' WITNESS LIST

Listed below are all of the witnesses Defendants intend to call at trial, whether live or by video. Defendants' deposition designations with objections are included as Exhibit X.A. In addition to the witnesses listed below, Defendants reserve the right to call in their case-in-chief witnesses listed on Plaintiff's witness list. Defendants further reserve the right to revise this list in accordance with any subsequent Court rulings or for good cause shown.

Defendants further reserve the right to call: (1) additional witnesses to provide foundational testimony should any party contest the authenticity or admissibility of any material proffered at trial; (2) additional witnesses necessitated by any of the Court's pretrial or trial rulings, or to respond to issues raised after the submission of witness lists; and (3) any substitute witnesses for any identified witness whose employment or other relationship with a company changes such that he or she is no longer able, available, or willing to testify on that company's behalf at trial. To the extent Defendants intend to call a substitute witness pursuant to this paragraph, Defendants will provide reasonable notice to Plaintiff after becoming aware of the need for calling the witness. The notice shall include the identity and expected testimony of the substitute witness and the basis, including relevant facts and circumstances, for calling the substitute witness.

Live[7]

1. Any witness identified on Plaintiff's live witness list
2. Agovino, Eric
3. Bray, June
4. Burchard, Philip

[7] The identification of a witness on this list is not an indication or representation that Defendants control a witness or can compel his or her attendance at trial, and thus, Defendants reserve all rights to play or read the deposition testimony of any witness on this list who does not appear live at trial.

5. Carnevale, Robert
6. Farlow, Martin
7. Finchen, James
8. Fowdur, Lona
9. Grabowski, David
10. Green, Philip
11. Hughes, James
12. Jochum, Patrick
13. Julie, Staci
14. Korhman, Bruce
15. Malinow, Robert
16. McCormick, JinPing or DRL Representative
17. Meury, William
18. Patel, Amit
19. Ogman, Errol
20. Robinson, Sue
21. Rovner, Barry
22. Ryan, Charles
23. Silber, Seth
24. Singh, Ajay
25. Snyder, Julie
26. Solomon, David
27. Taglietti, Marco
28. Zakreski, Randall
29. Zimmerer, Rick

By video

1. Cavanaugh, Maureen
2. Curia, Katrina
3. Devlin, Mark
4. Gupta, Kapil
5. Gupta, Sanjay
6. Hernandez, Charlene
7. Lahman, Bob
8. Ludwig, Peter
9. Mears, Rachel
10. Nadkarni, Bharati
11. Nicholls, Scott
12. Rabinovic, Lauren
13. Venkatesan, Gopalakrishnan
14. Wilk, Diana

XI. RELIEF SOUGHT

1. SBA, on behalf of itself and the Class (as defined by Order of the Court), seeks damages pursuant to:

a. State antitrust statutes in Arizona, California, District of Columbia, Hawaii, Illinois, Iowa, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, West Virginia, and Wisconsin, and;

b. State consumer protection and deceptive trade practices statutes in California, Florida, Idaho, Illinois, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, and Utah.

2. SBA, on behalf of itself and the Class (as defined by Order of the Court), seeks equitable relief for unjust enrichment in the following jurisdictions: Alabama, Arizona, California, District of Columbia, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, and West Virginia.

3. SBA seeks damages for overcharges and double and/or treble damages as allowed under the relevant state laws, as well as applicable equitable relief, and costs of suit, including reasonable attorneys' fees, reimbursement of its costs and expenses, and any such other relief this Court deems appropriate.

Date:

United States District Judge

Date: September 30, 2021

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	/s/ *Elaine Johnston* M. Elaine Johnston **ALLEN & OVERY LLP** 1221 Avenue of the Americas New York, NY 10020 Tel: (212) 610-6300 elaine.johnston@allenovery.com John Roberti **ALLEN & OVERY LLP** 1101 New York Avenue, NW Washington, DC 20005 Tel: (202) 683-3862 john.roberti@allenovery.com ***Counsel for Defendants Merz GmbH & Co KGaA, Merz Pharmaceuticals GmbH, and Merz Pharma GmbH & Co. KGaA***